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09/787,806	04/26/2001	Brian Anthony Whittle	65,213-001	9829

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Robert L Kelly  
Dykema Gossett  
39577 Woodward Avenue Suite 300  
Bloomfield Hills, MI 48304-2820

EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/787,806

Applicant(s)

WHITTLE, BRIAN ANTHONY

Examiner

Simon J. Oh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment of 26 November 2002.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 2, 4, and 9-11 under 35 U.S.C. 102 as being anticipated by Takaichi *et al.* is hereby withdrawn.

### ***Claim Rejections - 35 USC § 103***

The rejection of Claims 1, 2, 5, and 6 under 35 U.S.C. 103 as being unpatentable over Wilen is hereby withdrawn.

The rejection of Claims 1, 2, 4, and 9-11 under 35 U.S.C. 103 as being unpatentable over Takaichi *et al.* is hereby withdrawn.

The rejection of Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaichi *et al.* in view of Wilen, Needleman *et al.*, Theeuwes, and Buysch *et al.* is maintained with respect to Claims 1 and 4-13. This rejection with respect to Claims 2 and 3 is rendered moot with their cancellation.

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Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaichi *et al.* in view of Wilen, Needleman *et al.*, Theeuwes, and Buysch *et al.*

The Takaichi *et al.* document discloses a method of stabilizing pharmaceutical compositions by the use of calcium oxide and particulate silicon dioxide to control moisture and restrict the interaction of water with other components of the composition (See Abstract; Page 2, Line 12 to Page 3, Line 22). The amount of calcium oxide to be included in the composition is not to exceed 1.0 % by weight (See Page 4, Lines 10-21). A sour agent is also to be used and may be an organic acid, including citric acid and ascorbic acid (See Page 6, Lines 11-15). Other components, such as binders, excipients, and disintegrators may also be included, and the composition may be prepared using methods already known in the art (See Page 6, Line 16 to Page 7, Line 5).

The Takaichi *et al.* patent does not teach a composition comprising magnesium sulfate, either as the sole anhydrous compound, or in combination with calcium oxide, with either compound not exceeding 10% by weight of the composition. The patent also does not teach a composition that further comprises an acid or acid salt and a carbonate or bicarbonate in an effervescent composition. The patent does not teach a composition that further comprises a sulfite or calcium lactate.

The Wilen patent teaches an effervescent pharmaceutical composition comprising dried magnesium sulfate, and an effervescent base, which may include sodium bicarbonate and citric acid (See Example 2). Although the precise amount of magnesium sulfate is left to be determined by one of ordinary skill in the art, based on the disclosure of a previous example (See

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Example 1), it would be obvious that magnesium sulfate would be present in a quantity less than 10% by weight of the composition.

The Needleman *et al.* patent teaches an effervescent composition (See Abstract). The effervescent agent in the composition comprises an alkaline carbonate salt, which may be chosen from a group comprising sodium bicarbonate, sodium carbonate, potassium bicarbonate, potassium carbonate, magnesium carbonate, calcium carbonate, and combinations thereof (See Column 2, Lines 24-41). The effervescent agent further comprises an acid, which may be chosen from a group comprising tartaric acid, maleic acid, lactic acid, citric acid, ascorbic acid, sodium sulfite, potassium sulfite, and combinations thereof (See Column 2, Lines 42-61). The composition further comprises an exothermic agent, which may be chosen from a list that includes calcium oxide and magnesium sulfate (See Column 3, Lines 3-20). Furthermore, Needleman *et al.* disclose a problem known in the prior art of the moisture sensitivity of effervescing ingredients, and the need to avoid contact with even ambient humidity in order to preserve the shelf life of an effervescing product (See Column 1, Lines 36-50).

The Theeuwes patent teaches an osmotic device that dispenses a drug by the use of a gas-generating means (See Abstract). The gas-generating means preferably comprises a solid acid component and a solid basic component. Among the acids that may be used is malic, tartaric, maleic, and citric acid. Alternately, their corresponding anhydrides may be used as well. The solid basic component is preferably includes the carbonates and bicarbonates of alkali metals and alkali earth metals and mixtures thereof (See Column 4, Line 60 to Column 5, Line 36). The patent also mentions the use of a water scavenging process to control the acid-base reaction of the effervescing action (See Column 5, Lines 37-50). An osmotically effective compound may

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also be included in the composition to aid in the effervescing action. Such compounds include magnesium sulfate, sodium carbonate, sodium sulfite, calcium bicarbonate, and calcium lactate; mixtures of these compounds may also be used (See Column 7, Lines 1-30).

The Buysch *et al.* patent is relied upon as a teaching reference that acknowledges the dessicating properties of calcium oxide and magnesium sulfate in the prior art (See Column 5, Lines 14-38).

It would be obvious to one of ordinary skill in the art to combine the teachings of Takaichi *et al.*, Wilen, Needleman *et al.*, Theeuwes, and Buysch *et al.* into the object of the instant application. Wilen, Needleman *et al.*, and Buysch *et al.* all teach various effervescent compositions. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. One of ordinary skill would be motivated to combine these three references in order to gain a more complete understanding of the substances that may be included in an effervescing composition. Based on the disclosure in Needleman *et al.* regarding the moisture sensitivity of effervescing compounds, one of ordinary skill would be motivated to combine the teachings Takaichi *et al.* and Buysch *et al.* with the combined teachings of Wilen, Needleman *et al.*, and Buysch *et al.* in order to formulate a composition that prevents interaction of water with the effervescing components of said composition, improving stability and shelf life. Thus, the invention as a whole is *prima facie* obvious.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 12 and 13 are objected to under 37 CFR 1.75 as being a substantial duplicate of Claims 4 and 5, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Response to Arguments***

Applicant's arguments filed 26 November 2002 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the nutritive value of calcium oxide and magnesium sulfate and the counteractive properties found in the combination of these ingredients) are not recited in the rejected claim(s). Although the claims

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are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, the applicant's arguments are based on what the examiner believes to be a narrow interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

The applicant argues that the Takaichi *et al.* reference teaches away from the present invention, primarily due to its disclosure that it is not desirable to use amounts of calcium oxide greater than 1% by weight of the composition. Nevertheless, by what the examiner believes to be a reasonable interpretation of the prior art, it is disclosed that it is still possible to have amounts of calcium oxide present from 0% to 1% by weight. This range is encompassed by the applicant's claimed range of weight percentage values of, by the examiner's interpretation, 0% to 10%. The disclosure of the prior art can be applied towards the instantly claimed invention because of the scope of Claim 4. In a new claim, the applicant has also claimed that calcium oxide is present in the instantly claimed composition in an amount ranging from 4% to 8% by weight. It is the position of the examiner that the applicant has not shown the criticality of the selection of this range that would render it patentable above the disclosure of the prior art. The examiner applies the same argument towards the limitations of Claim 15, drawn to anhydrous or calcined magnesium sulfate being present in the instantly claimed composition in an amount ranging from 1% to 5% by weight.



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The breadth of the instant claims is such that they cannot be found to be allowable above the prior art. The rejection of Claims 1 and 4-13 stands.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the

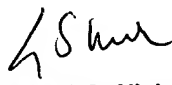
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organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj  
February 21, 2003

  
Gollamudi S. Kishore, PhD  
Primary Examiner  
Group 1600